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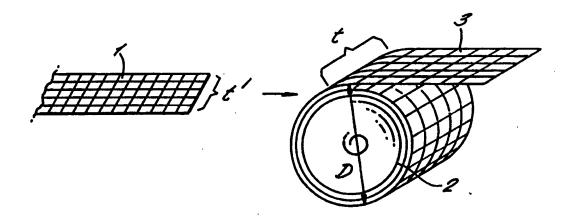
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#### (57) Abstract

A cylindrical, fibrous, porous joint spacer is provided, having excellent properties, flexibility of formation, and operability, which is intended to be implanted as a prosthesis between bones (8, 9) to be joined together. The joint spacer can be formed from a strip of fabric (1), which is comprised of bioabsorbable fibers and made by a knitting, weaving, non-woven or other technique. The fabric (1) is typically relatively narrow (e.g. 1 to 10 mm wide) and thin (e.g. 0.1 to 1.0 mm thick), depending on the intended application of the prosthetic device to be formed from the fabric (1). The joint spacer is made by wrapping said fabric (1) to yield a cylindrical body (2); and fixing the free end of the fabric (1) to the surface of the cylindrical body (2) so formed. The joint spacer can be implanted in conjunction with one or more fixation parts (14', 14"), to hold the joint spacer in place between the bones (15, 16) to be joined.

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### JOINT PROSTHESIS

The present invention relates to a biologically active joint prosthesis, and a method of its manufacture.

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It is known in the art to use synthetic, elastic, joint implants made of non-biodegradable plastics to replace damaged tissue joints, particularly joints connecting between small bones in the hands and feet. A typical biostable elastic joint prosthesis is composed of a spacer portion, which is positioned between the bones to be joined, and two elongated fixation portions, which are anchored in the bones to be joined. Such an artificial joint is available, for example, from Dow Corning, S.A., Valbourne Cedex. France, under the trade name Silastic®. The Silastic® implant is made of an elastomer material.

However, the use of joint prostheses manufactured of biostable polymers, polymer mixtures and elastomers can cause problems for the patient. One such problem with biostable joint prostheses is that the operated limb can only withstand a set amount of strain following the operation. For example, when a

Silastic® joint prosthesis is used to replace a finger joint, the operated hand cannot bear a strain of more than 5 kg-force, and over-straining may lead to breaking or wearing of the implant forming the joint prosthesis. Another problem of such biostable joint prosthesis is that loose particles may be released from the joint prosthesis, due to wearing, fatigue and/or corrosion, which particles may cause a chronic inflammation reaction, e.g., a synovitis, and/or osteological changes in the bone. Further, the inflammation reaction may cause tumefaction and pain in the joint, often to a degree which requires removal of the joint prosthesis.

the present application, describes a biodegradable joint prosthesis that is comprised of a spacer part and proximal and distal fixation parts, which are fixed to the bones to be joined. A joint prosthesis in accordance with WO 96/41596 can be implanted in the hand, wrist or foot area to entirely or partially replace a damaged joint. The spacer part of the joint prosthesis of WO 96/41596 keeps the bones to be joined at a desired distance from each other. The joint prosthesis is fixed to the bones by anchoring the proximal and distal fixation parts, respectively, in the two bones to be joined. The strength and ductility values of the fixation parts of the joint prosthesis of WO 96/41596 are chosen to allow bending of the operated joint shortly after implantation.

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The spacer part of the joint prosthesis of WO 96/41596 is important to the function of the prosthesis. In order to obtain a desired porosity (typically, a pore size of between 50  $\mu$ m and 1000  $\mu$ m), the spacer part of WO 96/41596 is preferably formed of a fibrous, three dimensional, partly porous structure of biodegradable fibers, which fibers have a typical thickness of between 1 and 300  $\mu$ m.

To produce that spacer part, the biodegradable fibers can be woven or knit or formed into a non-woven fabric and, then, folded or wrapped into a three-dimensional, pillow-like, porous structure. The spacer part of WO 96/41596 can also be produced from: (I) a continuous fiber blank using three dimensional weaving, knitting or twisting techniques, wherein a desired length of the continuous fiber blank is cut for each spacer part; (ii) biodegradable fibers which are cut into desired lengths and are bound together using a biodegradable binding blank; or (iii) a biodegradable, continuous, polymer blank which is treated to produce open porosity therein.

The shape of the spacer part of WO 96/41596 preferably corresponds

to the space between the bones to be joined by the joint prosthesis. Accordingly,

that spacer part may have the shape of a pillow, a cylinder, an ellipsoid, (flattened)

ball, cubic or rectangular prism, or other three dimensional structure which, as well as

possible, fills the space constructed for the spacer part between the bones to be

joined. The spacer part of WO 96/41596 is advantageously elastic, and it may not

contain any sharp and/or hard edges or angles which could cause mechanical

irritation of the surrounding tissue.

According to the present invention, a cylindrical, fibrous, porous joint spacer is provided, having excellent properties, flexibility of formation, and operability, which is intended to be implanted as a prosthesis between bones to be joined together. The joint spacer of the present invention can be formed from a strip of fabric, which is comprised of bioabsorbable fibers and made by a knitting, weaving, non-woven or other technique. The fabric is typically relatively narrow

(e.g. 1 to 10 mm wide) and thin (e.g. 1 to 1.0 mm thick), depending on the intended application of the prosthetic device to be formed from the fabric. Under the present invention, the joint spacer is made by wrapping said fabric to yield a cylindrical body, and fixing the free end of the fabric to the surface of the cylindrical body so formed. The joint spacer of the present invention can be implanted in conjunction with one or more fixation parts, to hold the joint spacer in place between the bones to be joined.

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The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings, in which:

- Fig. 1 illustrates the wrapping of a fabric to form a cylindrical body;
- Fig. 2 illustrates the fixing, by sewing, of the end of the fabric to the surface of the cylindrical body;
- Fig. 3 illustrates the fixing, by glueing, of the end of the fabric to the surface of the cylindrical body;
- Fig. 4 illustrates various fabrics that can be used in the present invention, wherein each such fabric has a different thickness and/or tightness of its fibers;
- Fig. 5 illustrates a fabric that can be used in the present invention, wherein the fabric is made of curled or spirally bent fibers;
- Fig. 6 illustrates a cylindrical body, wherein the cylindrical body is thinner at its center and thicker at its outer edges;
- Fig. 7 illustrates the wrapping of a fabric with a glueing film to form a cylindrical body;
  - Fig. 8 illustrates a porous cylindrical body, wherein the cylindrical

body has longitudinal vertical pores.

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FIGS. 9A to 9C illustrate various arrangements between bones and a cylindrical body.

FIGS. 10A to 10C illustrate a joint prosthesis comprised of a cylindrical body and fixation pin.

FIGS. 11 A and 11 B illustrate a cylindrical body as a partial prosthesis on the synovial cartilage surface, located at the proximal end of a tibia.

FIG. 12 illustrates a prosthesis comprising two cylindrical bodies and two fixation parts, wherein a cavity is formed between the two cylindrical bodies.

FIG. 13 illustrates a cylindrical body implanted between two bones, wherein the cylindrical body contains a circular fissure to simulate a synovial cavity.

The present invention relates to an implantable, cylindrical, fibrous

prosthesis, having improved properties and functional characteristics, and a method for its manufacture.

As shown by FIG. 1, the joint spacer of the present invention is manufactured from a fibrous fabric 1 that is wrapped to form a cylindrical body 2. The size of the cylindrical body so formed is characterized by its diameter "D" and its thickness "t", as illustrated in FIG. 1. According to FIGS. 1, 2, and 3, the free end of the fabric 3 is fixed to the surface of the cylindrical body, e.g., by sewing with a bioabsorbable suture 4, or by glueing with a bioabsorbable polymer melt or solution 5.

Manufacturing the cylindrical body 2 by wrapping the fabric yields

several advantages over the prior art. The diameter D of the cylindrical body can be varied easily and conveniently by varying the length of the fabric used to form the cylindrical body. Moreover, the surgeon can easily make D smaller in the operation room, if necessary, by opening the fixation (4 or 5) of the cylindrical body,

attaching the new free end of the fabric onto the cylindrical body. Likewise, the thickness t of the cylindrical body 2 can be varied easily by selecting fabrics having different widths t', as shown in FIG. 1.

The porosity of the cylindrical body 2 also can be advantageously 10 varied in several ways. For example, the porosity of the fabric 1 can be adjusted by varying the textile structure of the fabric. The pore size and distribution of the fabric 1 also can be adjusted by varying the thickness of the fibers used to make the fabric, i.e., by using thinner (e.g., 0.1 -10  $\mu$ m) fibers, thicker fibers (e.g., 10-500  $\mu$ m) or mixtures thereof in the fabric. The porosity of the fabric 1 (and the cylindrical body 2) also can be adjusted by varying the distribution and/or the diameter of the fibers used to make the fabric. Shown schematically in FIG. 4 are examples of some typical fabrics for use in the present invention, having various distributions and/or diameters of fibers. In addition to those illustrated in FIG. 4, numerous other fiber thicknesses and distributions in the fabric are possible under the present invention. 20 By varying the thickness and/or distribution and/or orientation of the fibers, and/or varying the knitting, weaving or non-woven technique used to make the fabric from such fibers, joint spacers can be prepared according to various specifications regarding load bearing properties, frictional properties and tissue growth properties.

As shown in FIG. 5, the fibers can be curled or twisted helically before

the manufacturing of the fabric 1. When such a fabric is wrapped, the resultant cylindrical body 2 is especially porous and elastic. The porosity of the cylindrical body 2 also can be varied by adjusting the tension applied to the fabric during the wrapping procedure. If low tension is used, the wrapped cylindrical body is loose and soft, and the thickness t of the cylindrical body can be almost the same as the width t' of the fabric. If high tension is used during the wrapping procedure, making the fabric tighter, harder and less porous, the thickness t of the resultant cylindrical body can be made smaller than the width t' of the fabric. Moreover, by varying the tension on the fabric during the wrapping procedure, a cylindrical body can be produced that has a varied thickness and porosity. As an example, when high tension is used at the beginning of the wrapping procedure and that tension is reduced progressively during the wrapping, a cylindrical body is produced having a middle section of high density and low thickness, as is illustrated in FIG. 6.

The fabric used to make the joint spacer of the present invention can be manufactured using fibers of a biodegradable polymer, co-polymer, polymer mixture or composition, or by combining various biodegradable polymer substances. When fibers of various biodegradable polymers are combined to make the fabric under the present invention, a joint spacer can be constructed that will degrade in the tissue in a non-uniform manner, as the various fibers making up the fabric may have different degradation rates in tissue. Alternatively, such non-uniform degradation of the joint spacer in tissue can be achieved under the invention by coating the fabric with a biodegradable material having a different degradation rate in tissue than the polymer or polymers used to make the fabric.

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In the medical, technical and patent literature, a multitude of

biodegradable polymers have been identified that are suitable as raw materials for making joint prostheses in accordance with the present invention. These include, for example, biodegradable aliphatic polyesters (cf., e.g., Vainionpaä, S. Rokkanen, P., and Törmälä, P. in Progr. Polym. Sci., 14 (1989) pp. 679-716; U.S. patent Nos. 4,743,257, 5,084,051, US 4,968,317; EPO Application No. 0423155; and PCT application No. PCT/FI93/00014); and polyester amides, polyorthoesters, polyanhydrides and polyphosphazenes (cf., e.g., C.T. Laurensin et al., J. Bigmed Mater. Res. 27 (1993), pp. 963-973).

When located in a joint cavity, the joint spacer of the present invention

will be covered and/or filled relatively rapidly with connective tissue. During that
biodegradation process, the joint spacer is replaced by a biological, fibrous tissue. As
a result, a new, biological, elastic fibrous tissue joint is obtained, which allows
moving of the joint bones by the surrounding muscles. As the new joint is formed
during the degradation process of the joint spacer, no foreign particles are released

that are chronically harmful to the patient's system, as can be the case with the socalled biostable joint prostheses. Thus, the joint spacer of the present invention
entirely eliminates the risks of such chronic complications caused by loose foreign
particles which are possible when using biostable joint prostheses.

To permit tissue growth within the joint spacer after its implantation,
the cylindrical body of the present invention is advantageously porous, with the pore
size varying between, e.g., 50 µm and 1000 µm. The pore size of the cylindrical
body can be varied, as illustrated above, in accordance with the desired mechanical
strength of the prosthesis and distance between the bones to be joined.

In one embodiment of the present invention, the wrapped fabric layers

of the cylindrical body are glued together, either by coating the surface of the fabric with another bioabsorbable polymer having a lower melting temperature than the fabric prior to wrapping the fabric, or by using a glueing bioabsorbable film 6 which is wrapped with the fabric 1, as shown in FIG. 7. The glueing of the fabric also can be accomplished using a solution of another bioabsorbable polymer. By using heat and/or pressure, the fabric coating or the glueing bioabsorbable film can be softened and/or melted to bind the wrapped fabric and form a solid cylindrical body.

Especially when using the glueing bioabsorbable film as above, it is possible to create oriented porosity and/or channels 7 in the perpendicular direction in relation to the even surfaces of the cylindrical body, as is illustrated schematically in FIG. 8. Such oriented pores and/or channels are advantageous where guided tissue regeneration (i.e., tissue growth directed in specific directions) is desired.

Under the present invention, the stiffness, flexibility, surface quality and porosity of the cylindrical body can be controlled by annealing the cylindrical body at elevated temperatures (typically, at a temperature  $T > T_g$ , where  $T_g$  is the glass transition temperature a fiber component of the cylindrical body), optimally in a suitable mold and under mechanical pressure. Annealing and the simultaneous mechanical pressure make the cylindrical body stiffer and, if the treatment is done in a mold, the form of the cylindrical body can be changed permanently, *e.g.*, the circular geometry of the cylindrical body can be flattened or its even surfaces can be made curved.

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The joint spacer of the present invention performs surprisingly well after implantation, whether one or both of the bones to be joined have had the joint surface removed. FIG. 9A shows as a cross-section of joint surfaces of two finger or

toe bones, 8 and 9. where the joint surface of both bones has been removed and the joint space is filled with a cylindrical body 10 having planar surfaces 10' and 10".

FIG 9B shows an embodiment where the joint surface is removed only from one bone 11 and not removed from the other bone 12 to be joined. To accommodate this situation, one surface 11' of the implanted cylindrical body 11 can be made concave and the other surface 11" can be made planar. FIG. 9C illustrates a case where both surfaces, 12' and 12", of the cylindrical body 12 are concave to fit the convex joint surfaces of the two bones to be joined.

The joint spacer (cylindrical body) of the present invention also can be used as in combination with different types of fixation parts (e.g., one or more pins, screws, bolts or rods, alone or in combination) arranged to fix the joint spacer to the bones to be joined, as is described in WO 96/41596 with regard to the spacer part and fixation parts of that reference. The fixation parts of the joint prosthesis in accordance with the present invention are characterized in that they are joined to the joint spacer to form a fixed and integrated entity, in a manner that the fixation parts and the joint spacer together form a flexible joint prosthesis. By way of the fixation parts, the joint spacer is kept between the bones to be joined, wherein by means of muscular power it is possible to bend the bones to be joined in relation to each other.

In accordance with the present invention, the fixation parts can be

20 manufactured of biodegradable polymer, polymer mixture or composition, by using
melt molding methods, such as injection molding or extrusion, or they can be formed
mechanically from a polymer blank to achieve the desired form. Self-reinforced
biodegradable compositions are particularly advantageous compositions for use as
raw materials in making the fixation parts in accordance with the present invention.

Such compositions are known in the art and have been described in publications such as U.S. Patent No. 4,743,257 and application No. WO 99/05312. Other biodegradable compositions may also be used to reinforce the fixation parts in accordance with the present invention, wherein the fixation part is reinforced by fibers, cut fibers, filaments or structures constructed thereof, such as braidings, threads, strings, non-woven structures, cloths, knittings etc., which reinforcement also is made of a biodegradable polymer, copolymer or polymer mixture.

Biodegradable compositions for making such reinforcements for the fixation part are known in the art, and many such polymers are identified in the references cited herein. The fixation part of the present invention can also be reinforced with fibers made of biodegradable ceramic material, such as bioglass or calcium phosphate (cf., e.g., Vainionpää, S., Rokkanen, P. and TormäJä, P. in Prog. Polym. Sci. 14 (1989), pp, 679-716).

by biodegradable organic and/or inorganic fibers or structures constructed thereof, can be manufactured by various methods known in plastic technology, e.g., by binding the reinforced structures, at least partially, to each other by bioabsorbable polymer, copolymer or polymer mixture (matrix), under conditions in which the matrix is in solution (or melted form) and a sufficiently homogeneous composition is formed from the matrix and the reinforcing agent. Injection molding, extrusion, winding, compression molding and other methods all can be used when combining the reinforcing fibers or the like and the matrix, and when forming that combination into prefabricates and/or implants. If desired, the fixation parts of the present invention can be porous in a similar manner to the joint spacer, wherein tissue growth

takes place in the open porosity of the fixation part from the surrounding tissue and, as a result, the fixation part is rapidly locked into its place.

The implants (joint spacer and fixation part) of the present invention may also include various additives to facilitate the processability of the material (for example stabilizers, antioxidants, or softening agents) or to change its properties (for example softening agents or ceramic chemicals in powder form or biostable fibers, such a carbon fibers) or to facilitate its use (e.g., coloring agents). The fixation part of the present invention also can be constructed of the patient's own fibrous tissue, such as tendon or ligament tissues, by manipulating a sufficiently long part of a tendon or ligament extending from one bone to be joined to the other such bone, in such a manner that the joint spacer is placed between the bones and the tendon or ligament penetrates the spacer part.

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According to one advantageous embodiment of the invention, the joint spacer and/or fixation part contain a bioactive agent or agents, such as antibiotics, chemotherapeutic agents, agents accelerating wound healing, agents inducing the forming of cartilage collagen, growth hormones, anticoagulant (such as heparin), etc. Bioactive mediums of this type are particularly advantageous in clinical use, because, in addition to the mechanic effect, they have biochemical effects (for example, accelerating the growth of fibrous and/or cartilage tissue), medical and other effects in human tissues.

The fixation part of the present invention can have a rigid or flexible structure. A rigid fixation part typically comprises a rod, bar, screw or pin, which at its stem is connected to the joint spacer and whose point is inside the bone to be joined. A profiling (such as a screw thread, various scales or steps) on the surface of

a fixation part of this type facilitates the locking of the fixation part into the hole
made inside the bone. An elastic fixation part can be comprised of, for example, a
cloth ("a veil") that is attached to or part of the joint spacer, and which is fixed (with
small absorbable pins or a suture) on the surface of the bone to be joined. Such an
elastic fixation part can also be comprised of one or more loops of absorbing suture
which are used for fixing the joint spacer to the bone to be joined.

FIG. 10 illustrates a schematic view of one application of the joint prosthesis according to the invention, to be used for joining together small bones (such as hand and feet bones).

FIG. 10A is a schematic figure of the bones 15 and 16, as seen from the side, i.e., from a position parallel to the bending direction of the joint, wherein the joint provided with a joint prosthesis is straight.

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FIG. 10B is a schematic figure of the bones 15 and 16, as seen from the side, i.e. from a position parallel to the bending direction of the joint, wherein the joint provided with a joint prosthesis is bent.

FIG. 10C is a schematic figure of the bones 15 and 16, as seen from above, i.e., from a position perpendicular to the bending direction of the joint, the joint provided with a joint prosthesis is straight.

As shown in FIG. 10, a rod-like fixation part 14 traverses a cylindrical body 14, and the ends 14' and 14" of the fixation part are located inside of bones 15 and 16. The present invention can be implanted in numerous other configurations of fixation parts and joint spacers (spacer parts), as is known in the art and shown, for example, in FIGS. 1-5 of WO 96/41596.

As shown in FIG. 11A, moreover, the cylindrical body (joint spacer)

of the invention can be used as a partial prosthesis on a synovial joint surface 17. As is seen in the cross-sectional plane a-a in FIG 11B, the flat cylindrical body 18 is located in a cavity 19 in the cartilage surface 17, on the surface of the bone 20. The porous, fibrous cylindrical body 18 induces the formation of new cartilage into the cavity 19 during bioabsorption of the cylindrical body and its replacement with newly grown tissue. As a result of this process, a new cartilage surface is created in the damaged cavity 19. In one advantageous embodiment, the cylindrical body 18 is loaded with chondrocytes or some similar type of cells before implantation. In tissue engineering it is known that several types of cells can be taken from the patient, multiplied under cell culture conditions, loaded into a porous bioabsorbable joint spacer (cylindrical body) and implanted into the patient to facilitate the healing of tissue trauma or deficiency.

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In another advantageous embodiment of the present invention, the prosthesis comprises two cylindrical bodies, which can be located parallel to one another in the joint cavity. In such a configuration, a vertical cavity is left between the cylindrical bodies, simulating the synovial joint cavity. As shown in FIG. 12, cylindrical bodies 21 and 22 are fixed to bones 25 and 26 with nail-like fixation parts 23 and 24, so that a synovial cavity-like space 27 is left between cylindrical bodies 21 and 22. When the patient moves the joint following such an implantation, the cylindrical bodies 21 and 22 glide in relation to each other and the synovial cavity-like space can remain inside the growing fibrous joint.

In another advantageous embodiment of the invention shown in FIG.

12, the contacting surfaces of cylindrical bodies 21 and 22, which contacting surfaces form the walls of the cavity 27, can be coated with hyaline cartilage cells and/or with

growth factors or other bioactive substances (or with another bioabsorbable polymer that releases growth factors), promoting the growth of hyaline cartilage or the formation of a cartilage layer on the cavity surfaces of the growing joint. In addition, as shown in FIG. 12, the surfaces of the cylindrical bodies 21 and 22 that are in contact with the bones 25 and 26 can be coated with bone morphogenic proteins (BMP), or with another BMP releasing bioabsorbable polymer to facilitate ossification of each cylindrical body 21 and 22 into the corresponding bone.

Another manner of simulating a synovial cavity under the present invention is illustrated by FIG. 13 As shown in that figure, a flat hole or circular fissure 28 is located inside the cylindrical body 29.

#### CLAIMS:

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1. A prosthesis for implantation between bones to be joined, comprising: a porous joint spacer made by wrapping a bioabsorbable fabric into a cylindrical body.

- 2. A prosthesis as claimed in claim 1, further characterised in that the porosity of the joint spacer is about 50  $\mu m$  to 1000  $\mu m$ .
- 3. A prosthesis as claimed in claim 1 or claim 2, further characterised in that the porous joint spacer is made by wrapping into the cylindrical body a bioabsorbable film that binds with the bioabsorbable fabric.
- 4. A prosthesis as in any of claims 1 to 3, further characterised in that the bioabsorbable fabric is comprised of at least two compounds having different degradation rates in tissue.
  - 5. A prosthesis as in claim 4, further characterised in that the bioabsorbable fabric is coated with a material having a different degradation rate in tissue than the bioabsorbable fabric.
  - 6. A prosthesis in claim 4 or claim 5, further characterised in that the bioabsorbable fabric is made from two or more biodegradable-fibers having different degradation rates in tissue.

7. A prosthesis as in any of claims 1 to 6, further characterised in that the fabric is made from biodegradable fibers having a thickness of about 1 to 300  $\mu m$ .

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8. A prosthesis as in any of claims 1 to 7, further characterised in that the cylindrical body has a fixation part for fixing the body to the bone.

- 9. A prosthesis as in claim 8, further characterised in that the fixation part comprises at least one pin, screw, bolt or rod.
  - 10. A prosthesis as in claim 8, further characterised in that the fixation part is comprised of at least one thread, braid or cloth.
- 10 11. A prosthesis as in claim 8, further characterised in that the fixation part is comprised of part of the cylindrical body.
  - 12. A prosthesis as in claim 8, further characterised in that the fixation part is comprised of a bioabsorbable suture.

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- 13. A prosthesis as in claim 8, further characterised in that the fixation part is comprised of tissue.
- 14. A prosthesis for implantation between bones to be joined, comprising a first porous joint spacer made by wrapping a bioabsorbable fabric into a cylindrical body and a second porous joint spacer made by wrapping a bioabsorbable fabric into a cylindrical body, wherein, after implantation of the prosthesis in a patient, the first porous joint spacer and the second porous joint spacer are configured to form a cavity.

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- 15. A method forming a prosthesis for implantation between bones to be joined, comprising the steps of:
  - a) cutting a strip of a bioabsorbable fabric to a desired length;
  - b) wrapping the bioabsorbable fabric into a cylindrical body; and

c) attaching the free end of the cylindrical body to the cylindrical body.

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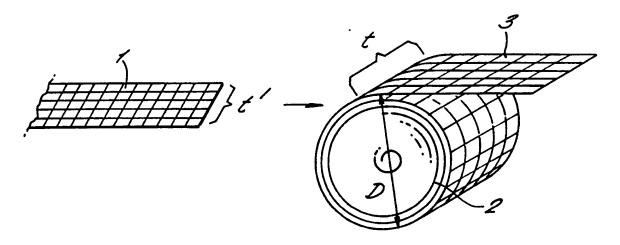


FIG. 2.

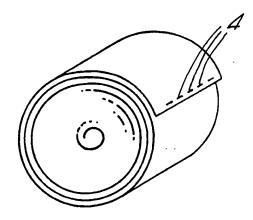
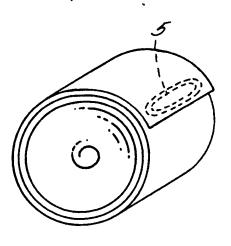
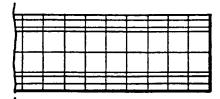
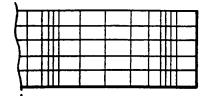


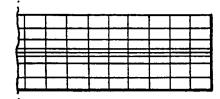
FIG. 3.

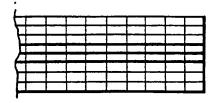


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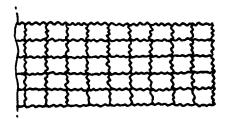


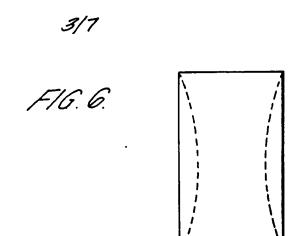


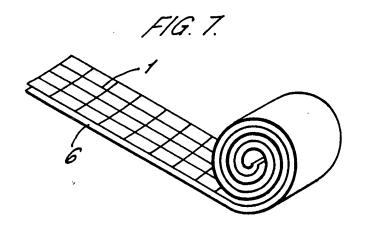


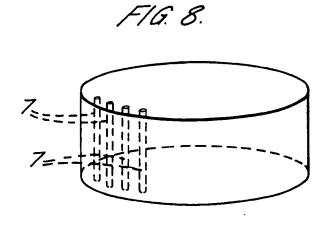


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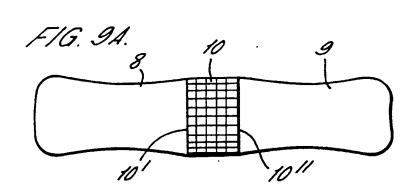




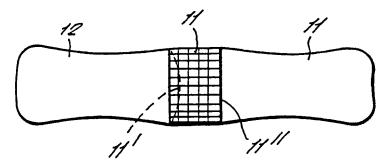




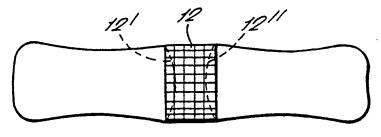
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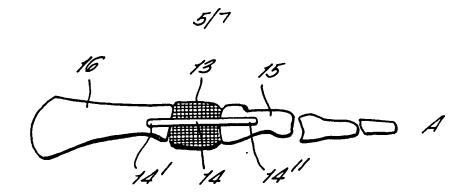


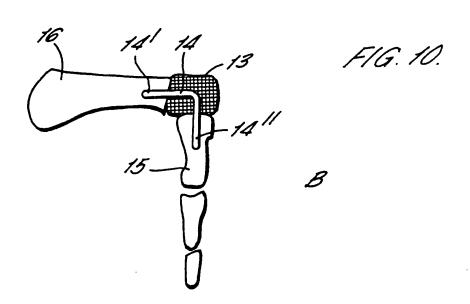
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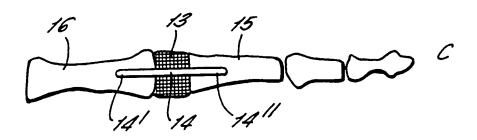


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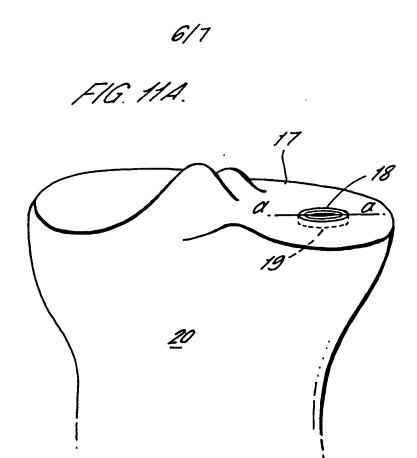


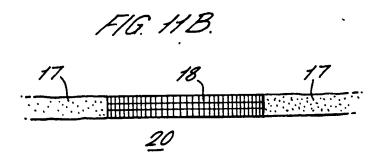






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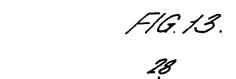




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national Application No PCT/EP 98/03030

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A. CLASS IPC 6	ification of subject matter A61F2/30 A61F2/42		
According t	to International Patent Classification (IPC) or to both national classific	ation and IPC	
B. FIELDS	SEARCHED		
Minimum de IPC 6	ocumentation searched (classification system followed by classificati $A61F$	on symbols)	
Documenta	ation searched other than minimum documentation to the extent that s	such documents are included in	the fields searched
Electronic o	data base consulted during the international search (name of data ba	ase and, where practical, searc	h terms used)
C. DOCUM	IENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.
Y A	FR 2 712 486 A (BRESLAVE) 24 May see the whole document	1995	1,3,15 14
Υ	EP 0 645 149 A (JOHNSON & JOHNSO 29 March 1995	N MEDICAL)	1,3,15
Α	see the whole document		5,14
Α	EP 0 773 008 A (SULZER ORTHOPÄDI 14 May 1997 see figures 1,2	E)	1,15
A	EP 0 526 682 A (OSCOBAL) 10 Febr see figure 15	uary 1993	1,15
A	WO 96 41596 A (BIOCON OY) 27 Dec cited in the application see the whole document	ember 1996	2,4-12
		-/	
X Fur	ther documents are listed in the continuation of box C.	X Patent family member	ers are listed in annex.
"A" docum consis "E" earlier filling "L" docum which citatio "O" docum	ent which may throw doubts on priority claim(s) or n is cited to establish the publication date of another on or other special reason (as specified) nent referring to an oral disclosure, use, exhibition or	or priority date and not incited to understand the invention  "X" document of particular recannot be considered in involve an inventive stell "Y" document of particular recannot be considered to document is combined to	after the international filling date in conflict with the application but principle or theory underlying the levance; the claimed invention over or cannot be considered to p when the document is taken alone levance; the claimed invention involve an inventive step when the with one or more other such docun being obvious to a person skilled
"P" docum	means nent published prior to the international filing date but than the priority date claimed	in the art.  "&" document member of the	
	actual completion of theinternational search	Date of mailing of the int	
	3 October 1998 mailing address of the ISA	19/10/1998  - Authorized officer	) 
	European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Klein, C	

1

i national Application No
PCT/EP 98/03030

	101/21 30/03030
Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
WO 96 24310 A (THE HOSPITAL FOR JOINT DISEASES, ORTHOPAEDIC INSTITUTE) 15 August 1996 see the whole document	2,4
US 5 207 712 A (COHEN) 4 May 1993 see figures 2,3,11	9,14
FR 2 458 275 A (BRISTOL-MYERS COMPANY) 2 January 1981 see figures 4,8	14
WO 95 22359 A (W.L. GORE & ASSOCIATES) 24 August 1995	
EP 0 454 645 A (MEDEVELOP) 30 October 1991	
US 4 313 232 A (HABAL) 2 February 1982	
·	
	DISEASES, ORTHOPAEDIC INSTITUTE) 15 August 1996 see the whole document  US 5 207 712 A (COHEN) 4 May 1993 see figures 2,3,11  FR 2 458 275 A (BRISTOL-MYERS COMPANY) 2 January 1981 see figures 4,8  WO 95 22359 A (W.L. GORE & ASSOCIATES) 24 August 1995  EP 0 454 645 A (MEDEVELOP) 30 October 1991

Information on patent family members

PCT/EP 98/03030

	tent document in search report	ı	Publication date		Patent family member(s)	Publication date
FR	2712486	Α	24-05-1995	NONE		
EP	645149	Α	29-03-1995	GB	2282328 A	05-04-1995
				AU	673769 B	21-11-1996
				AU	7430694 A	13-04-1995
				CA	2133028 A	30-03-1995 03-10-1995
				JP US	7250889 A 5514181 A	07-05-1996
				US	5514161 A 5595621 A	21-01-1997
				ZA ·	9407263 A	19-03-1996
EP	773008	Α	14-05-1997	JP	9164156 A	24-06-1997 
EP	526682	 А	10-02-1993	DE	59108588 D	10-04-1997
				JP	5261146 A	12-10-1993
				US	5397359 A	14-03-1995
WO	9641596	A	27-12-1996	FI	952884 A	14-12-1996
				AU	6127996 A	09-01-1997
				CA	2217291 A	27-12-1996
				EP	0831757 A	01-04-1998
WO	9624310	Α	15-08-1996	AU	693323 B	25-06-1998
				AU	4918996 A	27-08-1996
				CA	2212632 A	15-08-1996
				EP	0808142 A	26-11-1997
US	5207712	Α	04-05-1993	US	5425776 A	20-06-1995
FR	2458275	A	02-01-1981	GB	2077594 A	23-12-1981
				US	4246662 A	27-01-1981
				CA	1150002 A	19-07-1983
				DE	3021443 A	11-12-1980
				JP	56001147 A	08-01-1981
WO	9522359	Α	24-08-1995	AU	6943694 A	04-09-1995
				CA	2182500 A	24-08-1995
				EP	0744968 A	04-12-1996
				JP	9509081 T	16-09-1997

information on patent family members

Ir ational Application No
PCT/EP 98/03030

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 454645	A	30-10-1991	AT 114235 T AU 7760491 A DE 69105234 D WO 9116014 A	15-12-1994 11-11-1991 05-01-1995 31-10-1991
US 4313232	Α	02-02-1982	NONE	
WO 9012550	Α	01-11-1990	FI 891973 A AU 5233293 A AU 5530190 A EP 0422177 A JP 3505537 T	27-10-1990 17-02-1994 16-11-1990 17-04-1991 05-12-1991